AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listing, of claims in the application:

Listing of Claims:

Claims 1-34 (withdrawn)

Claim 35. (original) A method of purifying rhUG comprising the steps of:

a. providing a bacterial cell paste comprising bacterial cells capable of overexpressing rhUG;

b. lysing the bacterial cell paste to form a supernatant;

c. filtering the supernatant formed in step b through a first nominal molecular weight cut off (NMWCO) membrane to form a first permeate;

d. concentrating the first permeate formed in step c by the use of a second NMWCO membrane;

e. loading the concentrated permeate formed in step d onto an anion exchange column to form a first eluate;

f. concentrating the first eluate formed in step e by the use of a third NMWCO membrane to form a second concentrate;

g. loading the second concentrate formed in step f onto a Hydroxyapatite (HA) column to form a second eluate;

h. separating host-derived proteins from the rhUG in the second eluate formed in step g to provide purified rhUG; and

i. recovering the purified rhUG formed in step h.

Claim 36. (amended) The method of claim 35, wherein the synthetic gene expressed in the bacterial cells comprises at least one of a group comprising Seq. ID Nos. 1-4.

Claim 37. (original) The method of claim 35, wherein lysing comprises shearing.

Claim 38. (original) The method of claim 35, wherein between step b and step c, cell debris is removed by centrifugation.

Claim 39. (original) The method of claim 35, wherein the membrane of step b is about a 30K to 100K NMWCO membrane.

Claim 40. (original) The method of claim 39, wherein the filtering of step c comprises the use of a tangential flow filtration (TFF) system.

Claim 41. (original) The method of claim 35, wherein the membrane of step d is about a 5K NMWCO membrane.

Claim 42. (original) The method of claim 41, wherein the anion exchange column of step e is a Macro Q anion exchange column.

Claim 43. (amended) The method of claim 41, wherein the host-derived proteins of step h are separated with a Chelating ~~Sepharose~~ Fast Flow (CSFF) resin column.

Claim 44. (original) The method of claim 43, wherein the CSFF resin column comprises copper.

Claim 45. (original) The method of claim 44, wherein after step h a positively charged membrane is placed downstream of the CSFF column forming a pass through substantially free of host derived proteins.

Claim 46. (amended) The method of claim 45, wherein the positively charged membrane is a ~~Sartobind Q TFF~~ filtration membrane.

Claim 47. (original) The method of claim 35, wherein the second eluate is diafiltered through about a 30K NMWCO membrane.

Claim 48. (original) The method of claim 35, wherein the rhUG recovered in step i is substantially free of aggregates.

Claim 49. (amended) A method of purifying rhUG comprising the steps of:

a. providing bacterial cells capable of overexpressing rhUG;

b. lysing the bacterial cells to form a supernatant liquid;

c. filtering the liquid through a molecular weight cut off (NMWCO) membrane;

d. loading the liquid onto an ion exchange column;

e. separating host-derived proteins from the rhUG to provide purified rhUG; and

f. recovering the purified rhUG.

Claim 50. (amended) The method of claim 49, wherein the synthetic gene expressed in the bacterial cells comprises at least one of a group comprising Seq. ID Nos. 1-4.

Claim 51. (original) The method of claim 49, wherein the filtering of step c comprises the use of a tangential flow filtration (TFF) system.

Claim 52. (amended) The method of claim 49, wherein the ~~anion~~ ion exchange column of step d is a Macro Q anion exchange column.

Claim 53. (amended) The method of claim 49, wherein the host-derived proteins of step ~~h~~ e are separated with a Chelating ~~Sepharose~~ Fast Flow (CSFF) resin column.

Claim 54. (original) The method of claim 49, wherein the rhUG recovered in step ~~i~~ f is substantially free of aggregates.

Claim 55. (amended) A method of producing a pharmaceutical grade rhUG drug substance comprising the steps of:

a. providing a bacterial expression system capable of expressing rhUG;

b. inoculating a fermenter with an inoculum comprising the bacterial expression system to form a fermentation culture;

c. adding an induction agent to the fermentation culture to induce the expression of rhUG by the bacterial expression system;

d. harvesting the rhUG expressed in step c; and

e. purifying the rhUG harvested in step d, wherein the purifying step comprises the use of at least one filtration step and at least one ~~exhange~~ exchange column.

Claim 56. (original) An assay method for determining the potency of recombinant human uteroglobin in a sample which comprises:

(a) contacting a sample containing recombinant human uterogloblin with phospholipase A_2,

(b) introducing a labeled substrate to said sample,

(c) separating product from sample, and

(d) determining level of cleavage.

Claims 56-73 (withdrawn)

Claim 74. (amended) The method of claim 35 further comprising steps for determining the purity of recombinant human uteroglobin comprising, ~~A method for determining the purity of recombinant human uteroglobin which comprises,~~

(a) taking samples of intermediates at each step within the process of claim 35 and

(b) analyzing the process intermediates to determine purity relative to unpurified recombinant human uteroglobin or

(c) analyzing the process intermediates to determine purity relative to purified recombinant human uteroglobin taken from the preceding step or steps of the process of claim 35.

Claim 75. (original) The method of claim 74, wherein process intermediates are analyzed by SDS-PAGE.

Claim 76. (original) The method of claim 74, wherein process intermediates are analyzed by rhUG ELISA.

Claim 77. (original) The method of claim 74, wherein process intermediates are analyzed by LAL.

Claim 78. (original) The method of claim 74, wherein process intermediates are analyzed for protein content.

Claims 79-100 (withdrawn)